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EXAMINER

ORWIG, KEVIN S

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,173	Applicant(s) HASHIMOTO ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2, and 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendments filed on Aug. 18, 2009 have been entered.

Status of the Claims

Claims 1, 2, and 5-9 are pending. Claim 1 has been amended; claims 3 and 4 are cancelled; claims 8 and 9 have been added; claim 9 is withdrawn. Claims 1, 2, and 5-8 are now under consideration. This Office Action is in response to the request for continued examination filed on Aug. 18, 2009.

Election/Restrictions

Newly submitted claim 9 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The inventions of claims 1, 2, and 5-8 (Group I) and claim 9 (Group II) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

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In the instant case the product as claimed can be used in a different process. Specifically, the patch can be used in a method to topically deliver a drug, such as ketoprofen.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 9 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

OBJECTIONS/REJECTIONS WITHDRAWN

The rejection of claims 1, 2, and 5-7 under 35 U.S.C. 103(a) over TSURUDA is withdrawn in light of the claim amendments.

The rejection of claims 1 and 4 under 35 U.S.C. 103(a) over TSURUDA and CORDES is moot in light of the claim cancellations.

OBJECTIONS/REJECTIONS MAINTAINED

The double patenting rejections of record have been maintained in modified form as no action regarding these rejections has been taken by applicants at this time.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSURUDA (WO 01/68061; Published Sep. 20, 2001; Ref. BA on

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IDS dated Oct. 5, 2005) in view of IKEURA (WO 01/078690, Published Oct. 25, 2001) as evidenced by U.S. 6,924,410 and U.S. 2003/0149383.

Since the WO publications are in Japanese, the U.S. patent (6,924,410) to Tsuruda, and the U.S. patent application publication (2003/0149383) to Ikeura, which are the result of the national stage entries of the respective international applications, are relied upon herein as English language equivalents for all rejections based on WO 01/68061 and WO 01/078690. Column and line numbers refer to the '410 patent or the '383 application as appropriate.

1. Tsuruda discloses an ultraviolet-screening type patch comprising an organic ultraviolet (UV) absorbent and an inorganic UV screening agent (abstract). Tsuruda teaches that the patch of their invention preferably comprises a polyester backing (col. 4, lines 38-41; col. 10, lines 15-16) and an adhesive base (i.e. a pressure-sensitive adhesive) (col. 5, lines 44-50) on a surface of the backing layer (col. 4, lines 34-37). Tsuruda teaches that the adhesive base may contain the nonsteroidal anti-inflammatory drug (NSAID) ketoprofen, (col. 2, lines 38-41; col. 11, lines 25-43; col. 13, lines 3-17, Formulation 4; claim 1). Furthermore, Tsuruda teaches that, as the organic UV absorbent agent, the backing may comprise a benzotriazole derivative such as that represented by the general formula (1) in instant claim 1 (col. 2, lines 42-57, especially lines 50-52; claim 6). In particular, Tsuruda teaches benzotriazole species that are chloro substituted at the 5 position (i.e. X in formula (1) of instant claim 1) and having C₁₋₄ alkyl substituents at the 3' and 5' positions (i.e. R1 and R2 in formula (1) of instant claim 1) (col. 2, lines 50-52).

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2. Tsuruda teaches that the backing may contain titanium oxide (col. 2, lines 20-33; claim 3) and teaches that the adhesive base may comprise a styrene-isoprene-styrene block copolymer or polyisobutylene (col. 7, lines 7-14; claim 9). Tsuruda teaches that there is no need to add a UV absorbent into the base (i.e. adhesives) of their invention (col. 11, lines 60-61, and Formulations 1-4 in cols. 12 and 13).

3. Tsuruda teaches that polyester cloth is preferably used as the backing because it has a good feel and usage sense and that these materials preferably have a mass of $70\text{-}130\text{ g/cm}^2$ (col. 10, lines 15-24). It is noted that the instant claims recite, "...wherein the weight of the backing is $100\text{ g/m}^2\text{-}130\text{ g/m}^2$."

4. Since both Tsuruda and the instant application teach essentially the same invention, it is the examiner's position that the teaching of $70\text{-}130\text{ g/cm}^2$ by Tsuruda is a typographical error and that one of ordinary skill in the art would readily have recognized this error, which should be $70\text{-}130\text{ g/m}^2$. It is noted that similar polyester layers have weights per area on the order of 100 g/m^2 (see below). In further support of this position is the fact that both Tsuruda and the instant specification teach polyester cloth as the backing material (see Tsuruda col. 10, line 15 and paragraph [0034] of the instant specification). Since there is a difference of *four orders of magnitude* between the units of g/cm^2 and g/m^2 , it is reasonable to expect that one of these measurements is in error and that the same backing material for essentially the same invention (a UV-shielding skin patch) would not have a weight per area range this large. Furthermore, all of the examples of the instant application utilize a polyester woven fabric was used that had a weight of about 110 g/cm^2 . Either this is a similar typographical error, or it is

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evidence that the material used by Tsuruda would meet the instantly claimed limitations of the backing weight. It is noted that applicants have not addressed this issue. Applicants' silence on this issue is interpreted as an indication that the disclosure of Tsuruda of the units g/cm^2 (and the similar disclosure of g/cm^2 in Example 1 of the instant application) is indeed an error. Thus, one of skill in the art would have recognized this error and would only have needed Tsuruda, which teaches 70-130 g/cm^2 (*recognized by the skilled artisan to mean 70-130 g/m^2*) as the weight of the backing layer to envisage the instantly claimed backing weight. Based on this reasoning, Tsuruda alone meets the limitation of the backing layer weight. However, since applicants have failed to address this point, Ikeura is cited to show the obviousness of either weight range.

5. One of ordinary skill in the art would have envisaged the use of a polyester backing having a weight per area of between 100 and 130 g/m^2 since patch preparations using polyester backings of this type were known in the art at the time of the invention. For instance Ikeura discloses a transdermal NSAID-containing patch, wherein the NSAID is preferably ketoprofen (title; abstract; paragraphs [0014] and [0016]; Examples 1-5 and 8). Ikeura teaches the use of polyester backing layers (paragraph [0045]), and teaches that the backings preferably have a weight per unit area of $100 \pm 30 \text{ g/m}^2$ (paragraph [0047]). Ikeura teaches that such backings can be firmly affixed to flexion sites with vigorous movement such as an elbow or knee (paragraph [0047]). In light of the disclosure of Ikeura, it would have been *prima facie* obvious for the ordinary artisan to produce the patch taught by Tsuruda with a polyester

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backing of about 100 g/m^2 as taught by Ikeura. One would be motivated to do so if one wished to produce Tsuruda's patches for application to high flexion sites per Ikeura's teachings.

6. Thus, Tsuruda, either alone or in combination with Ikeura, teaches each and every aspect of the instant invention except for the *explicit* teaching that the UV transmittance is not more than 2.0% *under the condition of 3.0 mW/cm^2 of UV intensity*. However, Tsuruda teaches that the light transmittance of the patch is preferably not more than 15% under the condition of a UV intensity being about 0.14 mW/hr/cm^2 (col. 4, lines 25-26). Additionally, Tsuruda teaches that the phototransmission rate for the patches may be 2.0% or less (Table 1).

7. While it is not clear that the phototransmission (i.e. light transmittance) taught by Tsuruda is equivalent to the instantly claimed UV transmittance, the two parameters are measured in an essentially identical fashion. For instance, in paragraph [0036] the instant specification states, "As for the calculation of the ultraviolet transmittance, an ultraviolet dose transmitting through the backing is measured under a circumstance in which a direct sunlight irradiates enough to the backing, and the ultraviolet intensity without the above preparation is made 100, calculating each transmittance." By comparison, Tsuruda teaches irradiating a backing with sunlight to observe the UV intensity and then calculating the phototransmission rate of the backing on the basis of the UV intensity (col. 18, lines 19-38). However, Tsuruda discloses a phototransmission rate, and the actual UV transmittance of this light transmission is likely to be lower. Thus, based on the evidence and reasoning presented above, it is the examiner's

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position that the backings of Tsuruda would have a UV transmittance of not more than 2% measured under the instantly claimed conditions.

8. Since Tsuruda teaches the same compound in the same type of backing layer, the functional limitation is considered inherent because the prior art structure is substantially identical to that of the claimed invention. The MPEP states that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01.

9. Furthermore, even if the UV transmittance of Tsuruda's patches would not inherently meet the limitation of “not more than 2.0% under the condition of 3.0 mW/cm² of UV intensity”, in light of Tsuruda's teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to reduce the UV transmittance of the backing. A skilled artisan reading Tsuruda would be motivated to reduce the UV transmittance as much as possible since Tsuruda teaches that ultraviolet rays from the sun decompose the drug contained in the base and that photolyzed products can induce allergy to bring about adverse effects (col. 1, lines 23-28). It is the entire point of Tsuruda's disclosure to solve this problem by blocking UV light with UV screening agents (including the very same compounds instantly claimed). Tsuruda's

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teachings make it clear that a lower UV transmittance would better protect UV sensitive medications, as would be appreciated by the ordinary artisan. Further, Tsuruda teaches varying the amount of UV absorbents in the backing to increase the UV screening capability of the backing and improve drug stability (col. 3, lines 41-49). One would have been motivated to optimize the UV transmittance of the backing by reducing the transmittance as much as possible in order to provide maximum UV protection to the skin or to medication(s) (e.g. ketoprofen) contained in the base of the patch as taught by Tsuruda (abstract; col. 1, lines 5-6 and 59-64; col. 2, lines 34-37; col. 3, lines 45-49; col. 5, lines 6-15). Further, it is well within the skill of the ordinary artisan to optimize the amount of UV absorber(s) used in the backing depending on the drug contained in the patch (e.g. ketoprofen is known to be extremely photolabile). Therefore if an artisan wanted to produce a patch containing an extremely UV unstable drug (e.g. ketoprofen) one would have been motivated to reduce the UV transmittance of the backing as much as possible to prevent degradation of the medication as taught by Tsuruda.

10. Regarding new claim 8, the amount of drug remaining after a certain time at a certain measurement is, like the UV measurement conditions of claim 1, merely a property of the patch. Tsuruda, either alone or in combination with Ikeura, teaches all of the structural limitations of the patch. Thus, claim 8 is obvious over these references.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject

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matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Tsuruda fails to teach or suggest a patch having a UV transmittance of not more than 1.5% under the condition of 3.0 mW/cm² of UV intensity. Applicants further argue that Tsuruda does not *exemplify* a UV screening compound of formula (1) (response, p. 5-6).

First, Tsuruda, either alone or in combination with Ikeura, teaches each and every structural limitation of the rejected claims. The UV transmittance is a property of the patch structure as admitted by applicants. In particular, see the 1st sentence of the last paragraph of p. 7 of the response, which states that the UV absorbents used in the backings determine the fundamental properties of the patches that are obtained. Tsuruda teaches the instantly claimed UV absorbents (col. 2, lines 50-52; see below). Thus, the patch of Tsuruda, having the same structure as instantly claimed, must be capable of meeting the UV transmittance requirement if it were measured in the same way. Second, Tsuruda provides motivation for the skilled artisan to reduce the UV transmittance as much as possible. The artisan would be motivated to optimize the

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patch by selecting the best UV screening compounds and backing materials from those taught by Tsuruda. Doing so is no more than routine optimization. Third, Tsuruda teaches at least two compounds that are encompassed by formula 1, namely 2-(2'-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole, 2-(2'-hydroxy-3',5'-di-tert-butylphenyl)-5-chlorobenzotriazole (col. 2, lines 50-52). Thus, the compounds used in Tsuruda's backings include those instantly claimed, contrary to applicants' incorrect assertion. The fact that these particular compounds are not used in Tsuruda's examples does not negate the fact that they are taught as suitable compounds, are clearly intended embodiments of Tsuruda's disclosure, and are merely obvious choices in light of Tsuruda.

The MPEP states that patents are relevant as prior art for all they contain. See MPEP § 2123. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The MPEP further states that, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005) (reference

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disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component).

Moreover, the examiner disagrees that Tsuruda fails to suggest a patch having a UV transmittance of less than 2.0%, even under the UV intensity conditions instantly claimed. As set forth *supra*, Tsuruda is drawn to a patch structure that is identical to that instantly claimed. Tsuruda's patches feature the same backing materials and the same UV absorbing materials as those instantly claimed. The UV transmittance of the backing is determined by the identity of these materials as admitted by applicants (see the 1st sentence of the last paragraph of p. 7 of the response), which Tsuruda discloses. Tsuruda's patches can have a UV transmittance of less than 2.0% under conditions related to those instantly claimed (Table 1). Further, the teachings of Tsuruda would not only motivate the ordinary artisan to reduce the UV transmittance as much as possible when using photosensitive drugs (e.g. such as ketoprofen) in the patches (see the discussion *supra*), but would also lead one to do so.

It is well established that the motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Id.* at 1366, 80 USPQ2d at 1649. "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the improvement is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by

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improving a product or process is universal-and even common-sensical-we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references." *Id.* at 1368, 80 USPQ2d at 1651. In this case the artisan need not even combine references for such motivation. The teachings of Tsuruda clearly indicate that lowering the UV transmission of the patch is beneficial when UV sensitive drugs (e.g. ketoprofen) are used. The artisan would clearly be motivated to reduce the amount of UV transmittance based on Tsuruda's teachings, in order to obtain a patch in which NSAIDs like ketoprofen are as stable as possible, and would be capable of doing so, for example, by increasing the amount of UV absorber in the backing.

The argument that Tsuruda and the present invention are directed to two fundamentally different patches is not persuasive. As set forth *supra*, the patches of Tsuruda and those instantly claimed are substantially identical. In fact, the structure of the claimed patches *is* identical. It is only in the measurement of a property of the patches that the instant claims differ at all from Tsuruda. Thus, if any modification would need to be made to Tsuruda in order to arrive at the instant patches (and such has not been demonstrated), the modification would be extremely minor.

Applicants argue that one would not be motivated to modify Tsuruda's patches because the instant patches are measured with a different UV transmittance metric (response, p. 7).

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This argument is not only nonsensical, but does not address the motivation pointed to by the examiner, taken from Tsuruda's disclosure that less UV transmittance is better for a variety of reasons, thus motivating the artisan to make any instant modification required (however any structural difference between the two patches has not been demonstrated *or even claimed* at this time). As discussed above, the artisan would be motivated to reduce the UV transmittance of the patches as much as possible. In doing so, the artisan could have arrived at the instantly claimed invention by no more than routine experimentation (since all the same structural elements are taught by Tsuruda), regardless of whether or not the same UV measurements are actually conducted. It is noted that merely testing a product under conditions different from those in the prior art, and claiming the same product, or an obvious variant thereof, by way of the new test conditions does not make the product patentable.

Applicants are encouraged to provide actual data comparing Tsuruda's patch preparations under the same UV measurement conditions as instantly claimed in order to clarify exactly how different the two patch preparations actually are by directly comparable measurements in order to clarify this issue. No such data have been provided at this time. Additionally, applicants have not addressed the fact that Tsuruda discloses a phototransmission rate, which is distinct from a UV transmittance. The actual UV transmittance of Tsuruda's patches is likely to be lower than the phototransmission disclosed by Tsuruda since the UV represents only a small component of total light (e.g. sunlight). Moreover, Tsuruda teaches the use of the same materials for the very same purpose as that instantly claimed. Thus, one of skill in the

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art would have had a reasonable expectation of success in reducing the UV transmittance of Tsuruda's patches by no more than routine experimentation.

Applicants argue that the instantly claimed patch has superior and surprising properties (response, p. 10).

It is noted that Tsuruda directly teaches all of the effects applicants point to as being novel (see col. 11-12 of Tsuruda, elements numbered 1-6) with the exception of the specific UV measurement conditions instantly recited. It has been noted above that measurement by a different method does not make a product patentable. It is apparent that all applicants have done is merely select the optimal UV absorbent from Tsuruda's disclosure and test this patch in a way different from that disclosed by Tsuruda. This is no more than routine optimization, and cannot be considered inventive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 6,924,410

Claims 1, 2, and 5-8 are non-provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6,

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and 9 of U.S. Patent No. 6,924,410 in view of Ikeura. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '410 claims anticipates or renders obvious that of the instant claims. While most elements of instant claim 1 are anticipated by the '410 patent, the overall scope of the claims is not anticipated because the claims of the '410 patent do not recite a polyester backing, do not recite a *specific* benzotriazole derivative, and do not recite the instantly claimed UV transmittance measurement conditions. However, these elements, and thus the entire scope of the instant claims is rendered obvious since, polyester backings are commonly used in such adhesive patches (the preferred backing in the '410 patent). Tsuruda either teaches the weight of the backing layer (see the discussion of the error in Tsuruda at paragraph 4 above). Furthermore, '410 claim 6 recites benzotriazole derivatives, which are taught in the '410 patent. The instantly claimed UV transmittance values are either inherent to, or obvious variations of the '410 patent as discussed above.

Claims 1, 2, and 5-8 are directed to an invention not patentably distinct from claims 1-3, 6, and 9 of commonly assigned 6,924,410. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 6,924,410, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was

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made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

Claims 1, 2, and 5-8 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643